

# Clinical Development 101: General Principles

55-MINUTE ONLINE COURSE | LEVEL 1

## OVERVIEW

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**Clinical Development 101: General Principles** sets the stage for the entire clinical development process. Learn who conducts trials, how trials are conducted and the various regulatory elements that must be performed throughout Phases I-IV trials.

### Five Takeaways:

1. Understanding of the purposes for which clinical studies are conducted.
2. Fluency in clinical trial concepts such as control group, bias, blinding, randomization, and endpoints.
3. Knowledge of the study design criteria.
4. Required regulatory studies and data to enable follow-on studies.
5. Familiarity of the various clinical trial participants and their roles.

## AGENDA

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- **Clinical Development Introduction** describes the key milestones for drug development, specifically focusing on clinical development. Important terms including evidence-based medicine, translational medicine, and patient-centric clinical trials are explained. Finally, the purposes for which clinical trials are conducted are explored.
- **Clinical Trials: Basic Principles** explains how risk management is approached in terms of scientific method, Good Clinical Practices (GCPs), and trial design. Bias, blinding, randomization and endpoints are all explained in detail.
- **Conducting Clinical Trials** explains the various clinical trial participants and their roles, identifies the basics elements of a clinical trial protocol, describes informed consent, discusses inclusion/exclusion criteria, lists the steps in data management and reporting, and reviews the concept of clinical trial transparency.